CLAIMS

1. At least one computer readable medium collectively carrying a machine readable database identifying:

first patient eligibility criteria for a first clinical trial protocol; and

a first plurality of workflow tasks for said first clinical trial protocol, said first plurality of workflow tasks including post-enrollment workflow tasks.

2. A medium according to claim 1, wherein said database further identifies preliminary patient eligibility criteria applicable to said first clinical trial protocol.

3. A medium according to claim 1, wherein said database identifies a term by reference to a controlled medical terminology database.

4. A method according to claim 1, wherein said first plurality of workflow tasks includes data management tasks.

5. A method according to claim 4, wherein said post-enrollment workflow tasks include post-enrollment patient management tasks.

6. A method according to claim 4, wherein said data management tasks include an instruction for a clinician to complete a specified form.

7. A method according to claim 4, wherein said data management tasks include an instruction for a clinician to obtain informed consent of a patient.

8. A method according to claim 7, wherein said first plurality of workflow tasks includes an instruction to obtain specified patient medical information before said instruction to obtain informed consent.

9. A method according to claim 8, wherein said first plurality of workflow tasks includes a pre-enrollment instruction to obtain specified patient medical information after said instruction to obtain informed consent.

10. A method according to claim 7, wherein said data management tasks further include an instruction to enroll a patient into a clinical trial.

11. A method according to claim 1, wherein said data management tasks include an instruction to enroll a patient into a clinical trial.

12. At least one computer readable medium collectively carrying a machine readable database identifying:

a plurality of patient management tasks for a first clinical trial protocol; and

a plurality of data management tasks for said first clinical trial protocol.

13. A medium according to claim 12, wherein said database further identifies patient eligibility criteria applicable to said first clinical trial protocol.

14. A medium according to claim 12, wherein said database identifies a term by reference to a controlled medical terminology database.

15. A method according to claim 12, wherein said plurality of patient management tasks includes post-enrollment patient management tasks.

16. A method according to claim 12, wherein said plurality of data management tasks includes an instruction for a clinician to complete a specified form.

17. A method according to claim 12, wherein said plurality of data management tasks includes an instruction for a clinician to obtain informed consent of a patient.

18. A method according to claim 17, wherein said plurality of patient management tasks includes an instruction to obtain specified patient medical information before said instruction to obtain informed consent.

19. A method according to claim 18, wherein said plurality of patient management tasks further includes a pre-enrollment instruction to obtain specified patient medical information after said instruction to obtain informed consent.

20. A method according to claim 17, wherein said plurality of data management tasks further includes an instruction to enroll a patient into a clinical trial.

21. A method according to claim 12, wherein said plurality of data management tasks includes an instruction to enroll a patient into a clinical trial.

22 A clinical trials method, comprising the steps of:

storing a plurality of databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and protocol workflow tasks; and

providing access to individual ones of said databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria.

23. A method according to claim 22, further comprising the step of authorizing each of said clinical sites to perform trials of the clinical trial protocols to which the site is provided access.

24. A method according to claim 22, wherein said step of providing access comprises the step of downloading the database for a particular one of said protocols to a particular one of said clinical sites.

25. A method according to claim 22, wherein said step of providing access comprises the step of allowing a particular one of said clinical sites remote access to the database for a particular one of said protocols.

26. A method according to claim 22, further comprising the step of downloading at least a subset of said databases to a particular one of said clinical sites,

wherein said step of providing access comprises the step of allowing said particular clinical site to access one of the databases downloaded.

27. A method according to claim 22, further comprising the step of receiving said databases from a plurality of different protocol designers.

28. A method according to claim 22, wherein each of said databases identifies:

patient eligibility criteria for the respective clinical trial protocol; and

a plurality of workflow tasks for the respective clinical trial protocol, said plurality of workflow tasks including post-enrollment workflow tasks.

29. A method according to claim 28, wherein each of said databases further identifies preliminary patient eligibility criteria applicable to the respective clinical trial protocol.

30. A method according to claim 22, wherein each of said databases identifies:

a plurality of patient management tasks for the respective clinical trial protocol; and

a plurality of data management tasks for the respective clinical trial protocol.

31. At least one computer readable medium collectively carrying a library identifying a plurality of machine readable protocol databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and protocol workflow tasks.

32. A medium according to claim 31, further comprising means for providing access to individual ones of said protocol databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria.

33. A medium according to claim 31, wherein different ones of said protocol databases were prepared by different protocol designers.

34. A medium according to claim 31, wherein each of said protocol databases identifies:

patient eligibility criteria for the respective clinical trial protocol; and

a plurality of workflow tasks for the respective clinical trial protocol, said plurality of workflow tasks including post-enrollment workflow tasks.

35. A medium according to claim 34, wherein each of said protocol databases further identifies preliminary patient eligibility criteria applicable to the respective clinical trial protocol.

36. A medium according to claim 31, wherein each of said protocol databases identifies:

a plurality of patient management tasks for the respective clinical trial protocol; and

a plurality of data management tasks for the respective clinical trial protocol.

37. A medium according to claim 31, wherein at least one of said protocol databases identifies a term by reference to a controlled medical terminology database.

38. A medium according to claim 37, wherein each of said protocol databases identifies a term by reference to a controlled medical terminology database.

39. A medium according to claim 37, wherein each of a plurality of said protocol databases identifies a term by reference to a common controlled medical terminology database.

40. A medium according to claim 31, wherein different ones of said clinical trial protocols address different disease categories.

41. A medium according to claim 31, wherein each of said machine readable protocol databases includes software objects instantiated from a corresponding predefined set of object classes.

42. A medium according to claim 41, wherein all of said machine readable protocol databases include software objects instantiated from a common predefined set of object classes.

43. A medium according to claim 41, wherein a first one of said machine readable protocol databases includes software objects instantiated from a first predefined set of object

classes, and a second one of said machine readable protocol databases includes software objects instantiated from a second predefined set of object classes different from said first predefined set of object classes.

44. A medium according to claim 41, wherein the machine readable protocol databases are for clinical trial protocols in a plurality of disease categories,

and wherein the software objects included in each given one of said machine readable protocol databases are instantiated from a set of object classes which corresponds to and is specific to the disease category of the clinical trial protocol of the given protocol database.

45. A method for designing clinical trial protocols, comprising the steps of:

defining an initial group of first eligibility criteria for patients to be included in clinical trials of a particular clinical trial protocol; and

simulating patient accrual in dependence upon said initial group of first eligibility criteria.

46. A method according to claim 45, further comprising the step of revising said initial group of first eligibility criteria in dependence upon said step of simulating.

47. A method according to claim 46, further comprising the step of iteratively repeating said steps of simulating and revising, until the step of simulating predicts an acceptable patient accrual rate.

48. A method according to claim 45, wherein said step of defining an initial group of first eligibility criteria comprises the steps of:

selecting a first list of patient attributes from a plurality of pre-existing lists of patient attributes; and

establishing each of the first eligibility criteria in said initial group by assigning an initial condition to a corresponding one of the attributes in said first list, each of said criteria being satisfied only if a patient meets the condition assigned to the corresponding attribute, and each of said criteria being a member of the group consisting of inclusion criteria and exclusion criteria.

49. A method according to claim 45, further comprising the steps of:

selecting, from a plurality of pre-existing lists of patient attributes, a first one of said lists for use in defining preliminary eligibility criteria for said particular clinical trial protocol; and

establishing each of said preliminary eligibility criteria by assigning a condition to a corresponding one of the attributes in said first list, each of said criteria being satisfied only if a patient meets the condition assigned to the corresponding attribute, and each of said criteria being a member of the group consisting of inclusion criteria and exclusion criteria,

and wherein said first eligibility criteria are further eligibility criteria to be applied only to patients who have passed preliminary eligibility for said particular protocol as determined by said preliminary eligibility criteria.

50. A method according to claim 45, wherein said first eligibility criteria include both preliminary eligibility criteria and further eligibility criteria, said further eligibility criteria to be applied only to patients who have passed preliminary eligibility for said particular protocol as determined by said preliminary eligibility criteria.

51. A method for designing clinical trial protocols, comprising the steps of:

defining an initial group of first eligibility criteria for patients to be included in clinical trials of a particular clinical trial protocol; and

polling clinical sites for expected patient accrual in dependence upon said initial group of first eligibility criteria.

52. A method according to claim 51, further comprising the step of revising said initial group of first eligibility criteria in dependence upon said step of polling.

53. A method according to claim 52, further comprising the step of iteratively repeating said steps of polling and revising, until the step of polling predicts an acceptable total patient accrual rate.

54. A method according to claim 51, wherein said step of defining an initial group of first eligibility criteria comprises the steps of:

selecting a first list of patient attributes from a plurality of pre-existing lists of patient attributes; and

establishing each of the first eligibility criteria in said initial group by assigning an initial condition to a corresponding one of the attributes in said first list, each of said criteria being satisfied only if a patient meets the condition assigned to the corresponding attribute, and each of said criteria being a member of the group consisting of inclusion criteria and exclusion criteria.

55. A method according to claim 51, further comprising the steps of:

selecting, from a plurality of pre-existing lists of patient attributes, a first one of said lists for use in defining preliminary eligibility criteria for said particular clinical trial protocol; and

establishing each of said preliminary eligibility criteria by assigning a condition to a corresponding one of the attributes in said first list, each of said criteria being satisfied only if a patient meets the condition assigned to the corresponding attribute, and each of said criteria being a member of the group consisting of inclusion criteria and exclusion criteria,

and wherein said first eligibility criteria are further eligibility criteria to be applied only to patients who have passed preliminary eligibility for said particular protocol as determined by said preliminary eligibility criteria.

56. A method according to claim 51, wherein said first eligibility criteria include both preliminary eligibility criteria and further eligibility criteria, said further eligibility criteria to be applied only to patients who have passed preliminary eligibility for said particular protocol as determined by said preliminary eligibility criteria.

57. A method for clinical trials, comprising the steps of:

obtaining a first subset of patient information items about each of a plurality of patients;

comparing the first subset of patient information items about each of said plurality of patients against first eligibility criteria for a first clinical trial for a purpose of determining patient eligibility for said first clinical trial;

recording said first subset of patient information items about each of said patients to a database; and subsequently

comparing the first subset of patient information items about each of said patients from said database against second eligibility criteria for a second clinical trial for a purpose of determining patient eligibility for said second clinical trial.

58. A method according to claim 57, further comprising the steps of:

obtaining a second subset of patient information items about each of at least a subset of said plurality of patients, after said step of comparing the first subset of patient information items about each of said patients against first eligibility criteria for a first clinical trial for a purpose of determining patient eligibility for said first clinical trial; and

comparing the second subset of patient information items about each of said subset of patients against second eligibility criteria for said first clinical trial for a purpose of determining patient eligibility for said first clinical trial.

59. A method according to claim 58, further comprising the step of recording said second subset of patient information items about each of said subset of patients to said database.

60. A method according to claim 59, further comprising the step of comparing the second subset of patient information items about each of said subset of patients from said database against eligibility criteria for said second clinical trial for a purpose of determining patient eligibility for said second clinical trial.

61. A method according to claim 57, further comprising the steps of:

obtaining a preliminary subset of information items about each of a group of patients including said plurality of patients; and

comparing the preliminary subset of patient information items about each patient in said group of patients against preliminary eligibility criteria for said first clinical trial prior to said step of comparing the first subset of patient information items about each of said plurality of patients against first eligibility criteria.

62. A method according to claim 61, further comprising the step of recording said preliminary subset of patient information items about each patient in said group of patients to said database.

63. A method according to claim 61, further comprising the step of selecting said plurality of patients in dependence upon said step of comparing the preliminary subset of patient information items.

64. A method according to claim 57, wherein said step of recording said first subset of information items about each of said patients to a database includes the step of recording in said database an identity of the patient to which each of said information items relates.

65. A method according to claim 57, wherein at least one of said first eligibility criteria is defined according to a predefined controlled medical terminology.

66. A method for designing clinical trial protocols, comprising the steps of:

selecting, from a plurality of pre-existing lists of patient attributes, a first one of said lists for use in defining preliminary eligibility criteria for a first clinical trial protocol;

establishing each of said preliminary eligibility criteria by assigning a condition to a corresponding one of the attributes in said first list, each of said criteria being satisfied only if a patient meets the condition assigned to the corresponding attribute, and each of said criteria being a member of the group consisting of inclusion criteria and exclusion criteria; and

defining further eligibility criteria for the first clinical trial protocol, said further eligibility criteria to be applied only to patients who have passed preliminary eligibility for said first protocol as determined by said preliminary eligibility criteria.

67. A method according to claim 66, wherein said step of assigning a condition to a corresponding one of the attributes in said first list comprises the step of selecting a value for the attribute from a predetermined set of available values for the attribute.

68. A method according to claim 66, wherein said step of assigning a condition to a corresponding one of the attributes in said first list comprises the step of selecting a plurality of acceptable values for the attribute from a predetermined set of available values for the attribute.

69. A method according to claim 66, wherein said preliminary eligibility criteria includes a criterion corresponding to each of the attributes in said first list.

70. A method according to claim 66, wherein said preliminary eligibility criteria includes at least one inclusion criterion and at least one exclusion criterion.

71. A method according to claim 66, further comprising the steps of:

establishing each of a plurality of preliminary eligibility criteria for a second clinical trial protocol by assigning a condition to a corresponding one of the attributes in said first list; and

defining second further eligibility criteria for the second clinical trial protocol, said second further eligibility criteria to be applied only to patients who have passed preliminary eligibility for said second protocol as determined by said second preliminary eligibility criteria.

72. A method according to claim 66, comprising the steps of:

selecting, from said plurality of pre-existing lists of patient attributes, a second one of said lists for use in defining second preliminary eligibility criteria for a second clinical trial protocol;

establishing each of the criteria in said second preliminary eligibility criteria by assigning a condition to a corresponding one of the attributes in said second list; and

defining second further eligibility criteria for the second clinical trial protocol, said second further eligibility criteria to be applied only to patients who have passed preliminary eligibility for said second protocol as determined by said second preliminary eligibility criteria.

73. A method according to claim 66, further comprising the step of identifying said further eligibility criteria for the first clinical trial protocol in a first machine-readable protocol definition database in association with said first clinical trial protocol.

74. A method according to claim 66, wherein said step of defining further eligibility criteria comprises the step of selecting a term from a predefined controlled medical terminology.

75. A method for clinical trials, comprising the steps of:

at a first clinical site, obtaining a first subset of patient information items about each of a plurality of patients;

comparing the first subset of patient information items about each of said plurality of patients against first eligibility criteria for a first clinical trial for a purpose of determining patient eligibility for said first clinical trial; and

transmitting said first subset of patient information items about each of said patients to a central database in conjunction with an identification of said first clinical site.

76. A method according to claim 75, further comprising the steps of:

obtaining a second subset of patient information items about each of at least a subset of said plurality of patients, after said step of comparing the first subset of patient information items about each of said patients against first eligibility criteria for a first clinical trial for a purpose of determining patient eligibility for said first clinical trial; and

comparing the second subset of patient information items about each of said subset of patients against second eligibility criteria for said first clinical trial for a purpose of determining patient eligibility for said first clinical trial.

77. A method according to claim 76, further comprising the step of transmitting said second subset of patient information items about each of said subset of patients to said central database.

78. A method according to claim 75, further comprising the steps of:

obtaining a preliminary subset of information items about each of a group of patients including said plurality of patients; and

comparing the preliminary subset of patient information items about each patient in said group of patients against preliminary eligibility criteria for said first clinical trial prior to said step of comparing the first subset of patient information items about each of said plurality of patients against first eligibility criteria.

79. A method according to claim 78, further comprising the step of transmitting said preliminary subset of patient information items about each patient in said group of patients to said central database.

80. A method according to claim 78, further comprising the step of selecting said plurality of patients in dependence upon said step of comparing the preliminary subset of patient information items.

81. A method according to claim 75, wherein said step of transmitting said first subset of patient information items about each of said patients to a central database in conjunction with an identification of said first clinical site consists of the step of transmitting said first subset of patient information items about each of said patients in patient-anonymized form to said central database in conjunction with an identification of said first clinical site.

82. A method according to claim 75, wherein at least one of said first eligibility criteria is defined according to a predefined controlled medical terminology.

83. A method for clinical trials, comprising the steps of:

receiving from a first clinical site a first subset of patient information items about each of a first plurality of patients, the first subset of patient information items having been compared against first eligibility criteria for a first clinical trial for a purpose of determining patient eligibility for said first clinical trial; and

recording said first subset of patient information items in a central database.

84. A method according to claim 83, further comprising the steps of:

receiving from said first clinical site a second subset of patient information items about each of at least a subset of said first plurality of patients, the second subset of patient information items about each of said subset of patients having been compared against second eligibility criteria for said first clinical trial for a purpose of determining patient eligibility for said first clinical trial; and

recording said second subset of patient information items in said central database.

85. A method according to claim 83, further comprising the steps of:

receiving from said first clinical site a preliminary subset of information items about each of a group of patients including said first plurality of patients, the preliminary subset of patient information items about each patient in said group of patients having been compared against preliminary eligibility criteria for said first clinical trial; and

recording said preliminary subset of patient information items in said central database.

86. A method according to claim 85, wherein said first plurality of patients was selected in dependence upon said preliminary subset of patient information items.

87. A method according to claim 83, wherein said step of recording said first subset of patient information items in a central database includes the step of recording said first subset of patient information items in said central database in correspondence with an identity of said first clinical site.

88. A method according to claim 83, further comprising the steps of:

receiving from a second clinical site, a second subset of patient information items about each of a second plurality of patients, the second subset of patient information items having been compared against said first eligibility criteria for said first clinical trial for a purpose of determining patient eligibility for said first clinical trial; and

recording said second subset of patient information items in said central database.

89. A method according to claim 88,

wherein said step of recording said first subset of patient information items in a central database includes the step of recording said first subset of patient information items in said central database in correspondence with an identity of said first clinical site

and wherein said step of recording said second subset of patient information items in said central database includes the step of recording said second subset of patient information items in said central database in correspondence with an identity of said second clinical site.

90. A method according to claim 89, further comprising the step of querying said central database to simulate clinical site-specific patient accrual in dependence upon eligibility criteria for patients to be included in clinical trials of a particular clinical trial protocol.

91. A method according to claim 90, wherein said particular clinical trial protocol is different from said first clinical trial protocol.

92. A method according to claim 88, further comprising the steps of:

receiving from a clinical site, a third subset of patient information items about each of a third plurality of patients, the third subset of patient information items having been compared against said first eligibility criteria for a second clinical trial for a purpose of determining patient eligibility for said second clinical trial; and

recording said third subset of patient information items in said central database.

93. A method according to claim 92,

wherein said step of recording said first subset of patient information items in a central database includes the step of recording said first subset of patient information items in said central database in correspondence with an identity of said first clinical site,

wherein said step of recording said second subset of patient information items in said central database includes the step of recording said second subset of patient information items in said central database in correspondence with an identity of said second clinical site,

and wherein said step of recording said third subset of patient information items in a central database includes the step of recording said third subset of patient information items in said central database in correspondence with an identity of the clinical site from which said third subset of patient information was received.

94. A method according to claim 93, further comprising the step of querying said central database to simulate clinical site-specific patient accrual in dependence upon eligibility criteria for patients to be included in clinical trials of a particular clinical trial protocol.

95. A method according to claim 94, wherein said particular clinical trial protocol is different from both said first and second clinical trial protocols.

96. A method according to claim 83, wherein at least one of said first eligibility criteria is defined according to a predefined controlled medical terminology.

97. A clinical trials method, comprising the steps of:

managing progress of a first plurality of patients in a first clinical trial according to a first predefined workflow graph formed as part of a first clinical trial protocol;

recording the progress of each of the patients in said first plurality of patients through said first workflow graph; and

transmitting the recorded progress of each of the patients in said first plurality of patients to a central database.

98. A method according to claim 97, further comprising the steps of:

managing progress of a second plurality of patients in a second clinical trial according to a second predefined workflow graph formed as part of a second clinical trial protocol different from said first clinical trial protocol;

recording the progress of each of the patients in said second plurality of patients through said second workflow graph; and

transmitting the recorded progress of each of the patients in said second plurality of patients to said central database.

99. A method according to claim 97, wherein said first workflow graph connects a first plurality of workflow tasks,

and wherein said step of transmitting the recorded progress of each of the patients in said first plurality of patients to a central database comprises the step of transmitting to said central database an indication of which of workflow tasks have been performed on each of the patients in said first plurality of patients.

100. A method according to claim 99, wherein said step of transmitting the recorded progress of each of the patients in said first plurality of patients to a central database further comprises the step of transmitting to said central database patient medical status information collected from observation of each of the patients in said first plurality of patients.

101. A method according to claim 97, wherein said step of transmitting the recorded progress of each of the patients in said first plurality of patients to a central database comprises

the step of transmitting to said central database patient medical status information collected from observation of each of the patients in said first plurality of patients.

102. A method according to claim 101, wherein said patient medical status information includes at least one information item defined according to a predefined controlled medical terminology,

receiving from each of said sites information items about each of a respective plurality of patients, each of said information items being relevant to one or more of said patient eligibility criteria; and

storing said information items in a database.

103. A clinical trials method, comprising the steps of:

receiving from a first clinical site first notifications of progress of each of a first plurality of patients through a first predefined workflow graph formed as part of a first clinical trial and recording said first notifications in a database; and

receiving from said first clinical site second notifications of progress of each of a second plurality of patients through a second predefined workflow graph formed as part of a second clinical trial and recording said second notifications in said database.

104. A method according to claim 103, wherein said first workflow graph connects a first plurality of workflow tasks,

and wherein said first notifications of progress of each of a first plurality of patients through a first predefined workflow graph include indications of which of workflow tasks have been performed on each of the patients in said first plurality of patients.

105. A method according to claim 104, wherein said first notifications of progress further include patient medical status information collected from observation of patients in said first plurality of patients.

106. A method according to claim 105, wherein said patient medical status information includes at least one information item defined according to a predefined controlled medical terminology.

107. A method according to claim 103, further comprising the steps of:

receiving from a second clinical site third notifications of progress of each of a third plurality of patients through said first predefined workflow graph formed as part of said first clinical trial and recording said third notifications in said database.

108. A method according to claim 107, further comprising the step of evaluating the progress notifications received from at least said first and second clinical sites for a purpose of developing a metric comparing relative clinical trial performance of at least said first and second sites.

109. A method according to claim 103, further comprising the step of evaluating the progress notifications received from at least said first clinical site for a purpose of developing a metric of clinical trial performance of said first site.

110. A clinical trials method, comprising the steps of:

storing in a library of clinical trial sub-protocol components, a first clinical trial sub-protocol component identifying at least one member of the group consisting of a patient eligibility criterion and a protocol workflow task; and

assigning a first sub-protocol component level user access control to said first clinical trial sub-protocol component in said library.

111. A method according to claim 110, comprising the step of storing a plurality of databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and protocol workflow tasks,

wherein said step of storing a plurality of databases includes said step of storing a first clinical trial sub-protocol component.

112. A method according to claim 111, further comprising the step of providing access to individual ones of said databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria.

113. A method according to claim 110, wherein said step of assigning a first sub-protocol component level user access control to said first clinical trial sub-protocol component in said library comprises the steps of:

providing read/write access to said first clinical trial sub-protocol component by a first user; and

providing read but not write access to said said first clinical trial sub-protocol component by a second user.

114. A method according to claim 110, wherein said first clinical trial sub-protocol component includes first and second sub-protocol sub-components.

115. A method according to claim 114, further comprising the steps of:

assigning a first sub-protocol sub-component level user access control to said first sub-protocol sub-component; and

assigning a second sub-protocol sub-component level user access control to said second clinical trials sub-protocol sub-component in said library.

116. A method according to claim 110, further comprising the steps of:

storing in said library a second clinical trial sub-protocol component identifying at least one member of the group consisting of a patient eligibility criterion and a protocol workflow task; and

assigning a second sub-protocol component level user access control to said second clinical trial sub-protocol component in said library.

117. A method according to claim 116, wherein said first and second clinical trial sub-protocol components are both components of a common clinical trial protocol.

118. A method according to claim 116, wherein said first and second clinical trial sub-protocol components are components of different clinical trial protocols.

119. A method according to claim 116, wherein said step of assigning a first sub-protocol component level user access control to said first clinical trial sub-protocol component in said library comprises the step of providing read/write access to said first clinical trial sub-protocol component by a first user,

and wherein said step of assigning a second sub-protocol component level user access control to said second clinical trial sub-protocol component in said library comprises the step of providing read but not write access to said said second clinical trial sub-protocol component by said first user.

120 A clinical trials method, comprising the steps of:

storing a plurality of clinical trial sub-protocol components each identifying at least one member of the group consisting of a patient eligibility criterion and a protocol workflow task; and

providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users in accordance with predetermined sub-protocol component level access controls.

121. A method according to claim 120, comprising the step of storing a plurality of databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and protocol workflow tasks,

wherein said step of storing a plurality of databases includes said step of storing a plurality of clinical trial sub-protocol components.

122. A method according to claim 121, further comprising the step of providing access to individual ones of said databases by each of a plurality of clinical sites in accordance with predetermined site eligibility criteria.

123. A method according to claim 120, wherein said step of providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users comprises the steps of:

providing read/write access to a first one of said clinical trial sub-protocol components by a first one of said users; and

providing read but not write access to said first clinical trial sub-protocol component by a second one of said users.

124. A method according to claim 123, wherein said step of providing access to individual ones of said clinical trial sub-protocol components by each of a plurality of users further comprises the steps of:

providing read/write access to a second one of said clinical trial sub-protocol components by said second user.

125. A method according to claim 120, wherein a first one of said sub-protocol components includes first and second sub-protocol sub-components.

126. A method according to claim 125, further comprising the step of providing access to said clinical trials sub-protocol sub-components by each of a plurality of users in accordance with predetermined sub-protocol sub-component level access controls.

127. A method according to claim 120, further comprising the step of receiving said sub-protocol components from a plurality of different protocol designers.

128. At least one computer readable medium collectively carrying a library identifying a plurality of clinical trial sub-protocol components each identifying at least one member of the group consisting of patient eligibility criteria and protocol workflow tasks, said library further identifying sub-protocol component level user access controls for at least a subset of said sub-protocol components.

129. A medium according to claim 128, wherein said library further identifies a plurality of protocol databases each identifying, for a respective clinical trial protocol, at least one member of the group consisting of patient eligibility criteria and protocol workflow tasks,

wherein one of said clinical trial sub-protocol components is a component of one of said clinical trial protocols.

130. A medium according to claim 129, wherein said library further identifies protocol-level access controls which control access to individual ones of said databases by each of a plurality of clinical sites.

131. A medium according to claim 128, wherein said sub-protocol component level user access controls include a first control which provides read/write access to a first one of said clinical trial sub-protocol components by a first user and which further provides read but not write access to said first clinical trial sub-protocol component by a second user.

132. A medium according to claim 131, wherein said sub-protocol component level user access controls further include a third control which provides read/write access to a second one of said clinical trial sub-protocol components by said second user.

133. A medium according to claim 128, wherein a first one of said sub-protocol components includes first and second sub-protocol sub-components.

134. A medium according to claim 133, wherein said sub-protocol component level user access controls further include sub-protocol sub-component level user access controls.

135. A medium according to claim 128, wherein first and second ones of said sub-protocol components were prepared by different protocol designers.

136. A method according to claim 128, wherein first and second ones of said sub-protocol components are both components of a common clinical trial protocol.

137. A method according to claim 128, wherein first and second ones of said sub-protocol components are components of first and second different clinical trial protocols.

138. A medium according to claim 137, wherein said first and second clinical trial protocols address different disease categories.